UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

GARY A. FORST and BONITA A. FORST,

Plaintiffs,

v. Case No. 07-CV-612

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE,

Defendant.

ORDER

Plaintiffs Gary and Bonita Forst ("the Forsts") filed a products liability and personal injury action against Defendant Smithkline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") arising from Gary Forst's attempted suicide after using the prescription antidepressant Paxil CR®, manufactured by the defendant. The Forsts allege claims for negligence, negligent pharmaco-vigilance, strict liability, express warranty, implied warranty, fraud, negligent infliction of emotional distress, and loss of consortium. GSK now brings this motion for summary judgment on all claims. For the reasons set forth below, the court will deny the motion in its entirety. The court will also grant the Forsts' motion to stay all further proceedings. Finally, the court addresses additional motions regarding the confidentiality of supporting documents filed in connection with the motion for summary judgment.

BACKGROUND

Gary Forst ("Mr. Forst") began experiencing suicidal thoughts in 1995 and was subsequently diagnosed with Major Depressive Disorder. (Defendant's Proposed Findings of Fact ("D.'s PFOF") ¶¶ 1, 3, 4). Mr. Forst began taking a prescription antidepressant and was admitted to a hospital inpatient psychiatry unit. (D.'s PFOF ¶¶ 5, 8). During his hospitalization, Mr. Forst was seen by psychiatrist Dr. Paul Todd ("Dr. Todd") and placed on suicide precautions. (D.'s PFOF ¶ 9). Mr. Forst was discharged and placed on antidepressant medication. He continued taking prescription antidepressants for the next nine years. (D.'s PFOF ¶¶ 12-16).

In 2004, Mr. Forst suffered a relapse of Major Depression and was hospitalized twice due to his depression and suicidal thoughts. (D.'s PFOF ¶¶ 18-21). Following these hospitalizations, Dr. Todd switched Mr. Forst from his current prescription antidepressant to Paxil CR® ("Paxil"). (D.'s PFOF ¶ 24). Mr. Forst took Paxil for approximately two weeks before attempting suicide on March 17, 2004. In an attempt to kill himself, Mr. Forst first slashed his wrists with sheet metal, then drilled a chisel bit into his head. (D.'s PFOF ¶ 43).

Following his suicide attempt and discharge from the hospital, Mr. Forst met with his therapist, Peter Kenny, Ph.D. ("Dr. Kenny"). Mr. Forst informed Dr. Kenny that he attempted suicide because he was unhappy with the quality of work being done and sent to customers, and that he was not confident with new procedures at work that he found difficult to learn. (D.'s PFOF ¶ 46). Mr. Forst stopped taking Paxil

and resumed taking Zoloft, a different prescription antidepressant, which he presently takes. Zoloft carries warnings regarding suicidality similar to those carried by Paxil. (D.'s PFOF ¶ 50).

Paxil is a prescription medication designed to selectively inhibit the reuptake of serotonin. (D.'s PFOF ¶ 25). It is part of a wider class of antidepressants referred to as selective serotonin reuptake inhibitors, or "SSRI's." At the time of Mr. Forst's suicide attempt in March 2004, Paxil's prescribing information for physicians contained the following warnings regarding suicidality:

"PRECAUTIONS: *Suicide*"

> The possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for PAXIL CR should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

(D.'s PFOF ¶ 27). However, Paxil did not contain any specific warnings regarding an increased risk of suicidality caused by the drug itself.

In 2004, the FDA issued a Public Health Advisory regarding the need to closely monitor patients on antidepressants for a worsening of depression. This Public Health Advisory was issued shortly after Mr. Forst's suicide attempt, during his period of hospitalization. (D.'s PFOF ¶ 53). Sometime following the FDA's issuance of the Public Health Advisory, Bonita Forst ("Mrs. Forst") and her daughter each viewed a news story reporting on the advisory. (D.'s PFOF ¶ 57, Plaintiffs'

Response to D.'s PFOF, ¶ 57). The Forsts' son, Jeffrey Forst, also received anecdotal information regarding Paxil's link to a worsening of depression from a co-worker. He advised Mrs. Forst to conduct internet research on the topic. (D.'s PFOF ¶¶ 59, 60).

Approximately three years later, the Forsts filed two lawsuits against GSK arising from Mr. Forst's suicide attempt. On March 13, 2007, the Forsts filed an action in the Court of Common Pleas of Philadelphia County, Pennsylvania. (D.'s PFOF ¶ 82). On April 20, 2007, the plaintiffs filed a second lawsuit against GSK in the Circuit Court for Milwaukee County, Wisconsin. Both the Pennsylvania and Wisconsin lawsuits alleged that Paxil was the cause of Mr. Forst's suicide attempt. (D.'s PFOF ¶ 83). GSK subsequently removed the Wisconsin state court action to this court on July 3, 2007. (D.'s PFOF ¶ 84).

STANDARD

Summary judgment is appropriate where the moving party establishes that there is no genuine issue of material fact and that the party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "Material facts" are those facts which "might affect the outcome of the suit," and a dispute about a material fact is "genuine" if a reasonable finder of fact could find in favor of the nonmoving party. *See Anderson v. Liberty Lobby*, *Inc.*, 477 U.S. 242, 248 (1986). The party opposing summary judgment cannot simply rest on allegations or denials in its pleadings, but rather, it must also introduce affidavits or

other evidence setting forth specific facts showing a genuine issue for trial. *Anders v. Waste Mgmt. of Wis*., 463 F.3d 670, 675 (7th Cir. 2006). Finally, in conducting its review, the court views all facts and draws all reasonable inferences in favor of the nonmoving party. *Tanner v. Jupiter Realty Corp.*, 433 F.3d 913, 915 (7th Cir. 2006).

ANALYSIS

GSK first moves for summary judgment on all but one of the plaintiffs' claims, asserting that the claims are barred by the applicable statute of limitations. Alternatively, GSK argues that summary judgment is appropriate because the plaintiffs cannot establish a failure to warn by GSK; an element allegedly essential to all of the Forsts' claims. The court will address each argument in turn.

I. Statute of Limitations

A federal district court sitting in diversity must apply the forum state's substantive law, including statutes of limitations. *Evans ex rel. Evans v. Lederle Laboratories*, 167 F.3d 1106, 1111-12 (7th Cir. 1999) (citing *Guaranty Trust Co. v. York*, 326 U.S. 99, 109-10, 65 S.Ct. 1464, 89 L.Ed. 2079 (1945)). Thus, the applicable Wisconsin statute of limitations applies to the plaintiffs' claims. Under Wisconsin statute § 893.54(1), a three-year statute of limitations applies to plaintiffs' claims for negligence, negligent "pharmaco-vigilance," strict liability, express warranty, implied warranty, negligent infliction of emotional distress, and loss of consortium. The plaintiff's single remaining claim for fraud is governed by a six-year statute of limitations. Wis. Stat. § 893.93(1)(b).

The applicable three-year statute of limitations for the plaintiffs' claims[1] begins to run at some point after Mr. Forst's March 17, 2004 suicide attempt. However, the parties dispute whether it began to run before or after April 20, 2004. The Forsts filed their Wisconsin action on April 20, 2007, approximately three years and one month after Mr. Forst's suicide attempt. Therefore, if the court determines that the Forsts' claims accrued prior to April 20, 2004, then the claims are time-barred.

Under Wisconsin law, a cause of action accrues when the plaintiff "discovers, or in the exercise of reasonable diligence should have discovered, not only the fact of injury but also that the injury was probably caused by the defendant's conduct or product." *Nierengarten v. Lutheran Social Servs*., 219 Wis. 2d 686, 580 N.W.2d 320, 324-25 (1998) (quoting *Meracle v. Children's Service Society of Wis*., 149 Wis. 2d 19, 25-26, 437 N.W.2d 532, 534 (1989)). Whether the plaintiff exercised reasonable diligence is an objective test; the question is when the plaintiff should have known he had a claim against the defendant. *Howard v. Philip Morris USA, Inc*., 98 Fed. Appx. 535, 538 (7th Cir. 2004) (citing *Estate of Hegarty v. Beauchaine*, 249 Wis. 2d 142, 2001 WI App 300, 638 N.W.2d 355, 366 (Wis. Ct. App. 2001)). Reasonable diligence is defined as "such diligence as the great majority of persons would use in the same or similar circumstances." *Schmidt v. Northern States Power Co.*, 2006 WI App 201, ¶ 13, 296 Wis. 2d 813, 824, 724 N.W.2d 354, 359. Further, the issue of

[1]In the discussion that follows, the court uses the phrase "the claims" to refer to the claims for negligence, strict liability, express and implied warranty, negligent infliction of emotional distress, and loss of consortium that are subject to the three-year statute of limitations. The court's discussion does not apply to the fraud cause of action, which is subject to a longer statute of limitations. See Wis. Stat. § 893.94(1)(b).

reasonable diligence is ordinarily one of fact. *Spitler v. Dean*, 148 Wis. 2d 630, 638, 436 N.W.2d 308, 311 (1989) (citing *Borello v. U.S. Oil Co.*, 130 Wis. 2d 397, 404, 388 N.W.2d 140, 142-43 (1986)).

However, a plaintiff does not "discover" the cause of injury simply because he has an unsubstantiated, though correct, "hunch" about the source of the harm. A subjective lay person's guess or belief that "is not presently supportable" by objective medical information does not constitute knowledge that a defendant's conduct probably caused a particular injury. *See Borello*, 130 Wis. 2d at 412, 413 n.5. A person who has used reasonable diligence to secure medical advice that fails to verify the cause of his or her injury should be given the protection of one who is "blamelessly ignorant," even though a hunch about the injury's source later proves to be correct. *Id*. at 414. Thus, a plaintiff's correct "hunch" about the injury's cause does not trigger the statute of limitations to begin to run if the belief is not substantiated.

GSK argues that the plaintiffs' claims are time-barred under Wisconsin's three-year statute of limitations because the plaintiffs discovered, or should have discovered with reasonable diligence, that Paxil was a potential cause of Mr. Forst's suicide attempt prior to April 20, 2004. First, GSK argues that the Forsts *actually* identified Paxil as a possible cause of the suicide attempt prior to April 20, 2004, rendering their April 20, 2007 filing time-barred under the three-year statute of limitations. Alternatively, GSK asserts that the claims are time-barred because the

plaintiffs *should have* discovered Paxil as a potential cause of Mr. Forst's suicide attempt by exercising reasonable diligence because the information was publicly available.

However, issues of material fact exist as to whether the plaintiffs had actual knowledge that Paxil caused Mr. Forst's suicide attempt prior to April 20, 2004, and whether they should have discovered Paxil as a potential cause by exercising reasonable diligence. First, any suggestion or "hunch" by the plaintiffs prior to April 20, 2004, that Paxil was related to Mr. Forst's attempt does not constitute actual knowledge as a matter of law. GSK asserts that plaintiffs believed Paxil to be a cause of injury prior to April 20, 2004, because Mrs. Forst viewed an FDA Public Health Advisory, her son suggested that she conduct internet research regarding Paxil, and because Mr. Forst's doctors suggested as a form of therapy that his "unusual" thinking may be attributable to his medications. However, suggestions and hunches are not objective knowledge. Neither Mr. Forst's therapist nor his psychiatrist told Mr. Forst specifically that Paxil may have contributed to his suicide attempt. When asked whether Mr. Forst's therapy included suggesting that medication played a role in causing his suicide attempt, Dr. Todd responded "I'm not going to say that, no." (Docket #64, Ex. 47, Todd Dep. at 164:9-12).

Indeed, the Forsts could not objectively know that Paxil caused Mr. Forst's suicide attempt because his own psychiatrist did not know. Mrs. Forst specifically asked Dr. Todd whether Paxil played a role in Mr. Forst's attempt and he responded

that he "didn't know." (Todd Dep. at 162:4-18). Dr. Kenny also testified that Dr. Todd was unsure what caused Mr. Forst to attempt suicide. (Docket # 64, Ex. 51, Kenny Dep. at 32:10-33:2). Thus, the plaintiffs were never definitively told that Paxil was a potential cause of Mr. Forst's suicide attempt because Mr. Forst's treaters did not know what caused the attempt. Therefore, the court cannot conclude that the plaintiffs objectively knew that Paxil was a potential cause of Mr. Forst's injuries.

Second, there is a genuine issue of material fact regarding whether the plaintiffs should have identified Paxil as a possible cause of Mr. Forst's suicide attempt prior to April 20, 2004, by exercising reasonable diligence. Mrs. Forst pursued her "hunch" that Paxil may be related to her husband's suicide attempt by questioning his treating psychiatrist, Dr. Todd. However, Dr. Todd's answers failed to substantiate her theory. Whether Mrs. Forst's conversation with Dr. Todd constitutes reasonable diligence is a question of fact. *See Spitler*, 148 Wis. 2d at 638.

GSK notes that the plaintiffs failed to read Paxil warnings, conduct internet research, or contact GSK for information in the three weeks following Mr. Forst's suicide attempt and hospitalization. However, GSK wrongly assumes that these actions define "reasonable diligence" in discovering the cause of an injury. Mrs. Forst's husband had just attempted suicide by drilling a chisel bit into his head. He was then hospitalized for over a week. Given the context, a fact-finder could determine that Mrs. Forsts' questions to Dr. Todd constitute the diligence a "great

majority of persons would use in similar circumstances." *See Spitler*, 148 Wis. 2d at 638. Further, a fact-finder could determine that Mrs. Forst's "hunch" that Paxil may be related to Mr. Forst's injury was not "presently supportable" by Dr. Todd's answer and did not provide the requisite knowledge that Paxil may be connected to the suicide attempt. *Borello*, 130 Wis. 2d at 412-13. Thus, a genuine issue of matter remains regarding whether the Forsts should have discovered Paxil as a cause of Mr. Forst's suicide attempt by exercising reasonable diligence.

The court cannot conclude that the plaintiffs' causes of action accrued prior to April 20, 2004, as a matter of law. Therefore, the court will deny GSK's motion for summary judgment based on the Wisconsin statute of limitations.

II. Validity of the Failure to Warn Claims

GSK urges this court to grant summary judgment on all claims because the plaintiffs cannot establish a "failure to warn." GSK asserts that each of plaintiffs' claims, regardless of the underlying theory, is based on allegations that GSK failed to warn the plaintiffs and Mr. Forst's prescribing doctor of Paxil's possible adverse effects. However, GSK cites to no authority for this proposition, nor does it outline the elements of each of the plaintiffs' claims. Instead, GSK simply makes the assertion that the plaintiffs' eight claims all rise and fall with a "failure to warn" argument.[2] GSK has not supported this proposition and the court need not make

[2]The only support GSK provides for its assertion that each of plaintiffs' claims are based on a failure to warn is a footnote quoting phrases from the plaintiffs' complaint. (GSK's S.J. Br., footnote 8).

GSK's argument. *See Pelfresne v. Village of Williams Bay,* 917 F.2d 1017, 1023 (7th Cir. 1990).

However, to avoid any appearance that the court "sacrifice[s] substantive justice on the altar of administrative convenience," the court will address GSK's arguments. *See Luddington v. Indiana Bell Tel. Co.*, 966 F.2d 225, 230 (7th Cir. 1992). Under Wisconsin law, a failure to warn claim regarding pharmaceutical labeling requires: 1) that the defendant breached its duty to warn; and 2) that the breach caused the plaintiff's injuries. *See Kurer v. Parke, Davis & Co.*, 2004 WI App 74, ¶24, 272 Wis. 2d 390, 409, 679 N.W.2d 867, 876. In the instant case, genuine issues of material fact exist regarding GSK's duty to warn and the causal connection between GSK's failure to warn and Mr. Forst's injuries. Therefore, summary judgment is inappropriate on the merits of the plaintiffs' claims, even if GSK correctly asserts that each claim is based upon a failure to warn.

a. GSK's Duty to Warn

GSK first argues that it did not owe a duty to warn physicians or consumers about Paxil's possible adverse effects. GSK argues that no causal link has been established between Paxil and increased suicidality in patients over age 24. Therefore, any increased warnings to this effect would be wrong and violative of federal law. GSK cites the FDA's failure to conclude that SSRI's cause suidicidal behavior in patients over 24 after conducting a meta-analysis of 372 clinical trials.

However, GSK's argument that it has no duty to warn because no link exists between Paxil and increased suicidality as a matter of law is misleading.

The FDA's analysis does not definitively state that Paxil poses no increased risk of suicide attempts. The plaintiffs point to evidence that the FDA found patients taking Paxil were three times as likely to experience suicidality as compared to placebo, which was deemed statistically significant. Indeed, Dr. Russell Katz of the FDA stated that clinical trial data showed "causality." (Docket #64, Ex. 38, p. 275, 285). Further, the plaintiffs point to GSK's own 2006 analysis of its previous clinical trial data, which shows that a patient on Paxil was over six times as likely to attempt suicide as one on placebo. (Docket #64, Ex. 34). Mr. Roger Grimson, Ph.D., the plaintiffs' expert, also concluded that the positive association between Paxil and the suicidal events observed in the Paxil clinical trial data did not occur by chance, but are explained by causality. (Declaration of Roger Grimson, Ph.D ¶ 11). In addition, the plaintiffs point to medical literature that allegedly supports a causal relationship between Paxil and suicidality. (Docket # 64, Exs. 39-45). Therefore, the court cannot conclude that Paxil does not increase suicidality as a matter of law.

Further, the fact that the FDA did not require enhanced warnings at the time of Mr. Forst's suicide attempt does not insulate GSK from failure to warn claims. GSK argues that Paxil carried the only current FDA-approved warnings at the time of Mr. Forst's suicide attempt and that additional warnings "would have violated federal law." (GSK S.J. Mot., p. 30). However, drug manufacturers have an

affirmative duty to add new warnings to drug labels "as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.80(e)[3]. Therefore, if Paxil increases suicidality, GSK had a duty to update its labeling to warn against this enhanced risk. The plaintiffs present expert testimony concluding that Paxil causes an increased risk of suicidality. (Declaration of Joseph Glenmullen, M.D.; Declaration of Roger Grimson, Ph.D). Thus, viewing the evidence in the light most favorable to the plaintiffs, Paxil did pose a serious hazard not reflected in the drug's contemporaneous warnings. As a result, a genuine issue of material fact exists regarding whether GSK had a duty to warn about enhanced risk of suicidality. A reasonable fact-finder could determine that GSK had a duty to warn and the court cannot preclude plaintiffs' claims as a matter of law.

b. Causal Connection and the Learned Intermediary Doctrine

GSK next argues that no causal connection exists between the alleged failure to warn and Mr. Forst's injuries based on the "learned intermediary" doctrine. GSK argues that the learned intermediary doctrine precludes the plaintiffs' claims because a revised warning would not have affected Dr. Todd's decision to prescribe Paxil to Mr. Forst in March 2004. The "learned intermediary" doctrine allows a drug manufacturer to fulfill its duty to warn about the known dangers arising from use of

[3]The court cites to 21 C.F.R. § 201.80(e), which is the currently applicable statute. However, 21 C.F.R. § 201.57(e) was the applicable statute in 2004 when Gary Forst was prescribed Paxil. The statute was relocated to 21 C.F.R. § 201.80(e) in 2006.

its products and avoid liability for failure to warn by adequately warning the physician. *Phelps v. Sherwood Medical Industries,* 836 F.2d 296, 299 (7th Cir. 1987). Thus, application of the doctrine absolves drug manufacturers of the duty to warn a patient directly of a drug's dangerous propensities. *See Crisostomo v. Stanley*, 857 F.2d 1146, 1152 n.17 (7th Cir. 1988). However, the learned intermediary doctrine has not been adopted by all state courts. The Wisconsin Supreme Court has never determined whether the doctrine applies to drug manufacturers in Wisconsin and no lower Wisconsin court has adopted it. *Peters v. Astrazeneca*, *LP*, 417 F. Supp. 2d 1051, 1054 (W.D. Wis. 2006).

The court need not and will not apply the "learned intermediary" doctrine in this case. To echo our sister court in the Western District of Wisconsin, "this court will not create Wisconsin law without some indication that the state's highest court would apply the doctrine if given the opportunity to do so." *Peters*, 417 F. Supp. at 1054. Further, a genuine issue of material fact exists regarding whether GSK adequately warned Dr. Todd about Paxil's risks. Therefore, the "learned intermediary" doctrine would not preclude any "failure to warn" claim, even if the court determined that the doctrine applied in this case.

A jury could find that Dr. Todd was not adequately warned about Paxil's increased risk for suicidality and that such information would have affected his prescribing decision. GSK points to Dr. Todd's testimony that he was aware since medical school that "in the process of treating a person with depression, you went

through a period of time where they would be more suicidal." (D.'s S.J. Br., p. 34). However, there is no evidence that Dr. Todd knew that *Paxil* increased the risk of suicidality. General awareness that a period of increased suicidality may result from initiating treatment for depression with an antidepressant is different from knowledge that a particular drug may directly increase suicidality. Indeed, Dr. Todd testified that he was unaware of Paxil's risks. When asked whether he believed that Paxil caused suicidal behavior when prescribing it to Mr. Forst in 2004, Dr. Todd responded: "I did not have that information. And I think I can fairly well state that I didn't believe it caused suicidal behavior." (Todd Dep. at 208:8-14).

Further, an issue of material fact exists regarding a causal link between any allegedly inadequate warnings and Dr. Todd's decision to prescribe Paxil to Mr. Forst. GSK asserts that the plaintiffs fail to show that Dr. Todd would have refrained from prescribing Paxil if given a different warning, which the plaintiffs must do to sustain their claims. GSK points to Dr. Todd's testimony that his decision to prescribe Paxil to Mr. Forst was appropriate. However, when all the evidence is viewed in the light most favorable to the plaintiffs, a reasonable jury could conclude that Dr. Todd would not have prescribed Paxil if warned about increased suicidality. There is evidence in the record showing that Dr. Todd made changes to his prescribing habits after learning new information about the suicide risks of SSRI's like Paxil:

Q: [Attorney] Are the instructions that you give today, lets say for SSRI's generally, are they the same that you've been giving, say, for the last five years?

A: I don't think so. I think that I - certainly I - well, I have more knowledge about these things. I think I talk more about things that have been in the newspaper for them, because they always want to ask about suicide and things like that, so we go over that much more than before.

(Todd Depo, at 41:13-42:1). Further, a jury could weigh Dr. Todd's statements that he was unable to do a proper risk/benefit analysis at the time he prescribed Paxil to Mr. Forst in concluding that his decision to prescribe would have changed.

Q: You weren't able to convey [the suicide risks of Paxil] to [the Forsts], right?

A: I couldn't have told them any of this information specifically.

Q: And they weren't able to weight [sic] this information in the risk/benefit analysis themselves for the pros and cons?

A: I don't see how they could have.

Q: And you weren't able to do that either, correct?

A: I couldn't have engaged in that thought process.

Q: Were you able to get full, informed consent from [the Forsts] regarding this information at the time you prescribed Paxil to Mr. Forst?

A: Well, I couldn't have factored this into – because I had no knowledge of this at that time.

(Todd Dep., at 204:16-206:1). Finally, GSK repeatedly notes that Dr. Todd testified that he would not have changed his decision to prescribe Paxil to Mr. Forst. (D.'s S.J. Br., p. 36, D.'s Reply. Br., p. 14). However, when the cited testimony is

reviewed, the statements are less conclusive than GSK asserts. Dr. Todd responds only that he "doubts" information about Paxil's increased risk for suicidality would have changed his behavior and that he "doesn't know" whether he would want to change his behavior after viewing information about Paxil's suicide risk. (Docket #30, Ex. 3, Todd Dep., at 217). Thus, a genuine issue of material fact exists regarding whether Dr. Todd would have prescribed Paxil if given warnings about risks of increased suicidality in patients.

c. Causal Connection and Mr. Forst's Decision to Take Paxil

Finally, GSK argues that no causal connection exists between the alleged failure to warn and Mr. Forst's injuries because the plaintiffs fail to show that Mr. Forst would not have taken Paxil if properly warned. GSK relies upon *Kurer v. Parke, Davis & Company* for this proposition. 2004 WI App 74, 272 Wis. 2d 390, 679 N.W.2d 867. In *Kurer*, the Wisconsin Court of Appeals granted summary judgment to a drug manufacturer because the plaintiff failed to establish the requisite causal nexus between her oral contraceptive's allegedly inadequate warnings and her injuries. *Id*. at ¶ 2. The court required the plaintiff to establish causation by showing that she would have altered her behavior and avoided the injury in order to support her claim for negligence for failure to warn. *Id.* at ¶ 25.

The plaintiffs respond that *Kurer* does not represent the appropriate standard, but rather that Wisconsin law applies a "substantial factor test" to establish cause-in-fact. The plaintiffs cite *Michaels v. Mr. Heater, Inc*., in which the court

rejected the *Kurer* analysis and followed the "substantial factor" test articulated in a different products warning case. 411 F. Supp. 2d 992 (W.D. Wis. 2006). Under this analysis, the plaintiffs assert that they need only show that Paxil was a substantial factor in Mr. Forst's injuries. Thus, the court must first determine which standard applies to causation between Paxil and Mr. Forst's injuries.

This court applies *Kurer* to the instant case because it is the more analagous and authoritative case law. *Kurer* is a statement of Wisconsin state law by a Wisconsin state court. Further, *Kurer* involves claims of negligence against a drug manufacturer arising from an alleged failure to warn about potential side effects of the drug, just as in the instant case.[4] Though the court finds *Kurer* more applicable than *Michaels* in this instance, the court agrees with the *Michaels* statement that tort actions are not usually appropriate for disposition by summary judgment because they "generally encompass a multitude of factual issues and abstract concepts that become elusive when applied to varying concrete factual situations." 411 F.Supp.2d at 1001. (citing *Gracyalny v. Westinghouse Elec. Corp*., 723 F.2d 1311, 1316 (7th Cir. 1983); *Adelman-Tremblay v. Jewel Companies, Inc*., 859 F.2d 517, 518 (7th Cir. 1988)). This court will not grant summary judgment to GSK on the issue of

[4]This court applies the *Kurer* case because of its analogous facts. In deciding *Michaels*, the Federal District Court of the Western District of Wisconsin also had to choose between conflicting case law and similarly applied the case law most analagous to the facts before it. However, the Western District concluded that the Wisconsin Court of Appeals case *Tanner v. Shoupe*, 228 Wis.2d 357 (Ct. App. 1999), was more analagous to the case before it than *Kurer* and applied *Tanner*'s causation standard. *See Michaels*, 411 F.Supp.2d at 1006. ("Moreover, the facts of this case are more analogous to those confronted by the court in *Tanner* than in *Kurer*."). Thus, our sister court employed the same reasoning process, but reached an opposite conclusion due to the facts at issue.

causation, though it applies *Kurer*'s causal nexus between a drug's inadequate warnings and the resulting injuries.

The record suggests that Mr. Forst may not have continued taking Paxil if warned about an increased risk for suicidality. As discussed above, a genuine issue of material fact exists regarding whether Dr. Todd would have prescribed Paxil if provided with enhanced warnings. Under the same reasoning, Dr. Todd may have chosen not to prescribe Paxil, or chosen to discontinue Mr. Forst's prescription if he learned of an enhanced risk of suicidality. Mr. Forst testified that he relied on Dr. Todd's judgment in deciding to take Paxil. (Docket #30, Ex. 5, G. Forst Dep., at 268:13-15). Therefore, viewing the evidence in the light most favorable to the plaintiffs, Mr. Forst would also have relied on Dr. Todd's judgment in not taking Paxil or discontinuing his prescription.

Further, GSK relies upon weak evidence to establish that Mr. Forst would not have ceased taking Paxil if provided with enhanced warnings. GSK points to Mr. Forst's testimony that he has not familiarized himself with the warnings on his current antidepressant, Zoloft. However, Mr. Forst also testified that he has not been concerned because "Zoloft is working fine." (G. Forst Dep., at 270:2). Viewing this evidence in the light most favorable to the plaintiffs, Mr. Forst's decision not to review warnings on his current prescription is the result of his positive reaction to the drug and does not establish a practice of never reading or considering drug warnings. Admittedly, GSK does not bear the burden to establish that Mr. Forst

would not have altered his behavior. However, considering the relative strength of the record supporting each side highlights the "genuine issue" to be decided by a jury in determining causation. Based on the aforementioned, the court cannot conclude as a matter of law that no causation exists between GSK's failure to warn and Mr. Forst's injuries.

III. Validity of the Fraud Claims

GSK argues that the plaintiffs' claims for fraud, negligent misrepresentation, and negligent over-promotion fail because they cannot show that GSK made a false representation upon which the plaintiffs relied. To prove fraud under Wisconsin law, a plaintiff must demonstrate: 1) a misrepresentation; 2) intent to defraud; 3) reliance upon the false representations; and 4) damages. *Mackenzie v. Miller Brewing Co.*, 2001 WI 23, ¶ 18, 241 Wis.2d 700, 716, 623 N.W.2d 739, 745. GSK asserts that the plaintiffs provide no evidence that either Dr. Todd or Mr. Forst relied upon any GSK representation in deciding to prescribe or take Paxil.

Contrary to GSK's assertions, evidence exists in the record that creates a genuine issue of material fact regarding whether the plaintiffs received and relied upon alleged misrepresentations. Dr. Todd testified that he received GSK information about Paxil from sources he relies upon in making prescribing decisions. First, Dr. Todd testified that he received information about Paxil directly from GSK sales representatives. (Dr. Todd Dep., at 173:12-15). Further, Dr. Todd received the Paxil's drug package insert, a source of information that he considers to be

particularly important in making his prescribing decisions. (Dr. Todd Dep., at 30:19-31:1, 36:17-37:8, 37:5, 173:20-25). He expects that such information will be accurate and complete regarding the side effects of a drug manufacturer's medications. (Dr. Todd Dep., at 174:1-6). Therefore, a reasonable jury could find that GSK provided Dr. Todd with information misrepresenting the safety of Paxil and that he relied upon these misrepresentations in prescribing the drug.

Dr. Todd's reliance on GSK misrepresentations can be imputed to the plaintiffs. Civil liability for misrepresentation exists when it is "forseeable and intended that a fraudulent misrepresentation will be repeated to third parties and acted upon by them." *State v. Timblin*, 2002 WI App 304, ¶ 31, 259 Wis.2d 299, 314, 657 N.W.2d 89, 97 (criminal case citing civil fraud standards from Restatement of Torts § 533 (1977)); *see also Chitwood v. A.O. Smith Harvestore Prods., Inc*., 170 Wis. 2d 622, 635, 489 N.W.2d 697 (Ct. App. 1992)). It is wholly forseeable to a drug manufacturer that its prescribing and side effect information will be communicated to and relied upon by patients, even when the drug company only interacts directly with prescribing physicians and not patients. Though GSK made no direct representations to the plaintiffs, the plaintiffs based their decisions regarding Paxil on the information and advice of Dr. Todd. (G. Forst Dep., at 268:13-15). This information, in turn, was based upon GSK representations. Therefore, a genuine issue of material fact exists regarding whether Dr. Todd and the plaintiffs relied upon GSK's alleged misrepresentations.

IV. Validity of the Express Warranty Claim

GSK argues that the plaintiffs' breach of express warranty claim fails because GSK made no affirmation of fact or promise to the plaintiffs regarding Paxil. GSK points to the Forsts' testimony that they did not read or receive any information provided by GSK to support this assertion. Under Wisconsin statute 402.313, "any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to that affirmation or promise." Wis. Stat. § 402.313(1)(a). However, the affirmation does not have to be the sole basis for the sale; it need only be "a factor in the purchase." *Ewers v. Eisenzopf*, 88 Wis. 2d 482, 488, 276 N.W.2d 802, 805 (1979); *See e.g. Manitowoc Marine Group, LLC v. Ameron Int'l Corp.*, 424 F. Supp. 2d 1119, 1129 (E.D. Wis. 2006).

The court cannot grant summary judgment on the breach of warranty claim. GSK predicates its argument on the fact that GSK did not communicate any affirmation *directly* to the Forsts. However, as noted in the previous section, Mr. Forst testified that he relied upon Dr. Todd's information and advice regarding Paxil. Dr. Todd received information about Paxil from a number of sources, including drug package inserts and visits from GSK sales representatives. Indeed, GSK does not argue that it made no affirmations about safety and effectiveness to Dr. Todd. A reasonable jury could find that GSK's representations to Dr. Todd, which were then communicated to the Forsts, constitute an affirmation forming a "basis of the

bargain" for Mr. Forst's use of Paxil. *See Knipe v. SmithKline Beecham*, 583 F.Supp.2d 602, 626 (E.D.Pa. 2008) ("In short, a jury could conclude, from such evidence, that these various representations to [Dr.] Durham and communicated indirectly to Plaintiffs were the basis of the bargain..."). Therefore, summary judgment on the breach of express warranty claim is inappropriate.

V. Punitive Damages

GSK argues that the Forsts are not entitled to punitive damages because they provided no evidence that GSK acted in a sufficiently outrageous manner under Wisconsin law. GSK asserts that because the scientific evidence shows no increased risk of suicidality in adults caused by Paxil, it could not intentionally disregard the safety of consumers by failing to disclose or warn of an increased risk that did not exist.

Wisconsin statute 895.043 states that a plaintiff may receive punitive damages "if evidence is submitted showing that the defendant acted maliciously toward the plaintiff or in an intentional disregard of the rights of the plaintiff." An intentional disregard of the plaintiff's rights requires that the defendant either act with a purpose to disregard those rights, or know that its conduct is "substantially certain to result in the plaintiff's rights being disregarded." *Wischer v. Mitsubishi Heavy Industries America, Inc*., 2005 WI 26, ¶ 7, 276 Wis. 2d 4, 13, 694 N.W.2d 320, 325. However, the statute does not require the defendant to intend to cause injury to the plaintiff.

Id. Instead, the statute merely requires the plaintiff to show that the defendant acted maliciously or intentionally disregarded his rights. *Id*.

The court previously addressed and rejected GSK's argument that no causal connection existed between Paxil and increased risk for suicidality in adults over age 24 as a matter of law. Therefore, the court will not foreclose punitive damages on this basis. A reasonable jury may find that GSK knew Paxil increased the risk for suicidality, based on its earlier clinic trial results and the testimony of the plaintiffs' experts. As a result, the jury may also find that GSK's conduct was "substantially certain" to result in the plaintiffs' rights being disregarded. Thus, the court will deny GSK's motion for summary judgment on the Forsts' claim for punitive damages.

VI. Motions Held in Abeyance

Resolution of GSK's motion for summary judgment requires that the court also address two motions currently held in abeyance pending this court's decision on the instant motion for summary judgment. Pursuant to a stipulation by the parties, the court entered an order holding the following motions in abeyance: 1) GSK's second motion for summary judgment on federal preemption grounds; and 2) the Forsts' renewed motion to stay the proceedings. The abeyance order specifies that the Forsts must file a response to the second motion for summary judgment within thirty (30) days if this court denies GSK's instant motion for summary judgment - as it has above. Thus, the court will order the Forsts to file a response to GSK's motion for summary judgment on federal preemption grounds.

The court's decision on GSK's first motion for summary judgment also triggers consideration of the Forsts' renewed motion to stay proceedings. The Forsts' motion urges the court to stay further proceedings pending the United States Supreme Court's decision in *Wyeth v. Levine*, a pharmaceutical products liability case. 944 A.2d 179 (Vt. 2006), cert. granted, 128 S.Ct. 1118 (2008). In their motion, the Forsts argue for stay because *Wyeth* addresses the same question of federal preemption as GSK's second motion for summary judgment, namely, whether federal law preempts state "failure to warn" claims when the drug in question met the FDA's labeling requirements at the time of injury. However, on March 4, 2009, the United States Supreme Court issued a decision in *Wyeth*. 555 U.S. ___ (2009), 2009 WL 529172 (2009). Therefore, the decision renders the Forsts' request for stay moot and the court will deny the motion.

VII. Additional Motions

The parties filed a number of additional motions related to GSK's summary judgment motion. The pending motions filed by the Forsts include the following: a) motion to strike evidence submitted by GSK in support of its motion for summary judgment; b) motion to unseal documents filed conditionally under seal in support of their summary judgment response; c) motion to file a response to GSK's responses to their additional proposed findings of fact; and d) motion to unseal documents filed conditionally under seal in support of their response to GSK's response to plaintiffs' additional proposed findings of fact. In addition, GSK filed a motion to strike the

Forsts' additional proposed findings of fact. The court will address each motion in turn.

a. Forsts' Motion to Strike Evidence

The Forsts urge this court to strike a number of exhibits filed by GSK in support of its motion for summary judgment because GSK failed to properly authenticate the exhibits. Specifically, the Forsts argue that GSK's attorney cannot authenticate Mr. Forst's medical records and that GSK's deposition extracts do not include a reporter's certification stating that they are true and correct copies. However, GSK filed addition authenticating documents and the Forsts decided not to pursue their motion to strike. The motion will be denied.

b. Motion to Unseal Documents Filed in Support of Plaintiffs' Opposition to GSK's Motion for Summary Judgment

The Forsts also seek the unsealing of exhibits filed in support of their opposition to GSK's motion for summary judgment. The Forsts filed the exhibits conditionally under seal and now ask the court to unseal 19 select documents, excluding Mr. Forst's medical records. GSK opposes the unsealing of 13 exhibits, arguing that they contain GSK's confidential commercial information protected under FDA regulations, Federal Rule of Civil Procedure 26(c)(1), and Wisconsin's Uniform Trade Secrets Act. GSK further asserts that the damage to GSK caused by exposure of the documents outweighs the plaintiffs' interest in disclosure. Specifically, GSK argues the following: a) disclosure will result in "snippets" of information being taken out of context and will make the company look bad; b)

disclosure will be bad for public health because negative publicity resulting from the "out of context snippets" will result in less use of medication by patients who need it; and c) disclosure will result in competitive injury because GSK's proprietary research and data analysis methods will be exposed.

The public has a legitimate interest in the record compiled in a legal proceeding because the public pays for the courts. *Citizens First Nat. Bank of Princeton v. Cincinnati Ins. Co.*, 178 F.3d 943, 944 (7th Cir. 1999). However, a party's property or privacy interest may, at times, override the public interest if there is good cause for sealing part of the record. *Id*. at 945. Federal Rule of Civil Procedure 26(c)(1) states that a court may issue an order protecting a "trade secret or other confidential research, development, or commercial information" from public disclosure "for good cause."

Regardless of Rule 26, there is "no absolute privilege for trade secrets and similar confidential information." *Federal Open Market Comm. of Fed. Reserve Sys. v. Merrill,* 443 U.S. 340, 362, 61 L. Ed. 2d 587, 99 S. Ct. 2800 (1979) (quoting 8 C. Wright & A. Miller, Federal Practice and Procedure § 2043, at 300 (1970)). Courts frequently afford only a limited protection instead of an automatic and complete protection against disclosure. *Id*. Further, any protection afforded by the court must be substantially justified. Indeed, the Seventh Circuit stated that it will deny outright any motion to maintain the confidentiality of information that fails to "analyze in detail, document by document, the propriety of secrecy, providing reasons and legal

citations." *Baxter Int'l, Inc. v. Abbott Labs*., 297 F.3d 544, 548 (7th Cir. 2002). To establish "good cause" and protect confidential business information under Rule 26(c), the company seeking confidentiality must show a "clearly defined and very serious injury" that will result from disclosure. *Andrew Corp. v. Rossi*, 180 F.R.D. 338, 341 (N.D. Ill. 1998) (citing *Culinary Foods, Inc. v. Raychem Corp*., 151 F.R.D. 297, 300 n.1 (N.D. Ill. 1993)).

To prevent disclosure, GSK must first go through document by document and establish that the exhibits at issue constitute trade secrets or confidential commercial information. *See Baxter Int'l*, 297 F.3d at 545 ("But those documents, usually a small subset of all discovery, that influence or underpin the judicial decision are open to public inspection unless they meet the definition of trade secrets or other categories of bona fide long-term confidentiality."). As described by the Wisconsin Trade Secrets Act, "trade secret" means any information that: 1) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and 2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Wis. Stat. § 134.90. However, all commercially valuable information does not constitute a trade secret, but instead, trade secrets are a "subset of all commercially valuable information." *IDX Systems Corp. v. Epic Systems Corp*., 285 F.3d 581, 583 (7th Cir. 2002).

As an initial matter, GSK does not oppose the unsealing of Exhibits 8 and 17 attached to the "Declaration of Bijan Esfandiari in Support of Plaintiffs' Opposition to GSK's Motion for Summary Judgment" (hereinafter, "Esfandiari Declaration"). Therefore, the court finds that no good cause exists to maintain confidentiality of this information and will unseal the exhibits.[5] Further, Exhibits 1, 5, and 11 attached to the Esfandiari Declaration have been unsealed by the District Court for the Northern District of Indiana. *See Cunningham v. Smithkline Beecham*, 2008 WL 2572076 (N.D. Ind., June 25, 2008). Thus, good cause does not exist to maintain confidentiality of the documents in the instant action and the court will similarly unseal them.

The court now turns to the remaining exhibits. GSK fails to establish that the individual documents at issue involve trade secrets or other similarly confidential commercial information. The court credits GSK's argument that disclosure of confidential information will generate harm by granting competitor insight into GSK's proprietary techniques and processes of analyzing data. However, GSK fails to specify how the documents in question and the information contained therein benefit its competitors.[6] Further, after reviewing the subject documents, the court does not

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[5]The Forsts request that Exhibits 26, 27, 62 and Exhibit A to Dr. Glenmullen's Report remain confidential because they constitute Mr. Forst's medical records. (Forst Mot. Unseal, n.1). The Forsts also withdraw their request to unseal Exhibit 13. (Forst Reply Mot. Unseal, n.4). Therefore, these exhibits will remain sealed.

[6]GSK argues that documents regarding submissions to the FDA are confidential. However, it admits that one type of data that can be disclosed under the FDA regulatory scheme is a drug's summary basis for approval. (GSK Opp. Mot. Unseal, p. 11) (citing 21 C.F.R. § 314.430(e)(2)). Exhibit 14 is the Summary Basis of Approval for Paxil. Therefore, the court will unseal this document.

independently conclude that the information derives independent economic value from remaining unknown, or that competitors could obtain economic value from its disclosure. The fact that GSK's general assertion is correct does not mean that it protects the exhibits at issue in the Forsts' motion.

GSK's remaining arguments against disclosure primarily assert that GSK will be harmed by disclosure of the information. However, the court does not find a document to be confidential merely because exposure may create a "chilling effect" on future GSK internal communications, or because it may create an unfavorable public perception of the company. In addition, the court does not reach this analysis. The court concludes that the subject exhibits do not contain trade secrets or other bona fide confidential information; therefore, the court does not proceed to weigh the harm to GSK against the interest of the public in disclosure. The court will grant the Forsts' motion to unseal.

c. Motion to File a Response to GSK's Responses to Plaintiffs' Additional Proposed Findings of Fact

The Forsts ask further leave of the court to respond to GSK's responses regarding the Forsts' proposed findings of fact. The local rules for the Eastern District of Wisconsin do not contemplate the filing of a response to the non-moving party's response to proposed findings of fact. *See* Civil L.R. 56.2. Further, the court chooses not to open the door to a never-ending progression of "responses to responses to responses" involving the proposed findings of fact. Therefore, the

court will deny the motion and strike the Forsts' response to GSK's response to the additional proposed findings of fact.

d. Motion to Unseal Documents Filed in Support of the Plaintiffs' Response to GSK's Response to Plaintiffs' Additional Proposed Findings of Fact

The court determined above that the Forsts' motion to file a response to GSK's response will be denied and the response will be stricken. Therefore, the court will deny the motion to unseal documents the Forsts filed in support as moot.

e. Motion to Strike Additional Proposed Findings of Fact

Finally, GSK urges the court to strike the Forsts' additional proposed findings of fact because they are irrelevant to the summary judgment motion. Under Civil Local Rule 56.2(b)(2), a non-moving party may present additional factual propositions relevant to the summary judgment motion. This court found the additional proposed facts largely unnecessary in deciding the instant summary judgment motion. However, "largely unnecessary" is not the same as irrelevant. The court sees no need to strike the additional proposed findings of fact.

Accordingly,

IT IS ORDERED that GSK's motion for summary judgment (Docket #28) be and the same is hereby **DENIED**;

IT IS FURTHER ORDERED that the Forsts' shall file a response to GSK's motion for summary judgment within thirty (30) days of the date of this order;

IT IS FURTHER ORDERED that the Forsts' renewed motion to stay all proceedings pending the Supreme Court's decision in *Wyeth v. Levine* (Docket #44) be and the same is hereby **DENIED as moot;**

IT IS FURTHER ORDERED that the Forsts' motion to strike evidence submitted by GSK in support of its motion for summary judgment (Docket #69) be and the same is hereby **DENIED**;

IT IS FURTHER ORDERED that the Forsts' motion to unseal documents that are being filed conditionally under seal (Docket #68) be and the same is hereby **GRANTED, in part**; the clerk of the court shall place in an open file Exhibits 1, 5, 7, 8, 9, 10, 11, 14, 17, 21, 22, 24, and 61 attached to the Declaration of Bijan Esfandiari in support of the plaintiffs' opposition to GSK's motion for summary judgment and Exhibit B to the Declaration of Roger Grimson, Ph.D. in support of plaintiffs' opposition to GSK's motion for summary judgment.

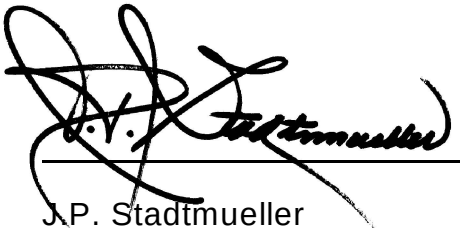
IT IS FURTHER ORDERED that the Forsts' motion to file a response to GSK's responses to plaintiffs' additional proposed findings of fact (Docket #97) be and the same is hereby **DENIED**; the response and corresponding attachments will be **STRICKEN**;

IT IS FURTHER ORDERED that the Forsts' motion to unseal documents filed conditionally under seal in support of plaintiffs' response to GSK's response to plaintiffs' additional proposed findings of fact (Docket #98) be and the same is hereby **DENIED** as moot;

IT IS FURTHER ORDERED that GSK's motion to strike the plaintiffs' proposed findings of fact (Docket #79) be and the same is hereby **DENIED**.

Dated at Milwaukee, Wisconsin, this 11th day of March, 2009.

BY THE COURT:



J.P. Stadtmueller
U.S. District Judge